

## REMARKS

In the Office Action mailed February 27, 2006, the Examiner has withdrawn claims 107-140 pursuant to 37 C.F.R. § 1.142(b). Applicant acknowledges, with traverse, the Examiner's withdrawal of the instant claims. Applicant has amended claim 63 to correct minor typographical errors therein.

Applicant notes with appreciation the Examiner considering the Information Disclosure Statement filed March 18, 2002, notwithstanding the instant Information Disclosure Statement being unsigned (by Applicant's previous attorney), prior to a first Office Action on the merits. As a courtesy to the Examiner, Applicant respectfully submits herewith a signed Information Disclosure Statement the content of which is identical to the unsigned Information Disclosure Statement filed March 18, 2002.

The Examiner has also indicated that U.S. Patent No. 4,186,745, which patent was listed in the Third Supplemental Information Disclosure Statement filed on June 20, 2005, was not considered "since the patent number and the Inventor does not match." The Examiner further states that "[i]t is not clear what patent applicant is attempting to submit for consideration" and that "[f]or this patent to be considered, Applicant needs to resubmit the IDS under the rules." Applicant respectfully points out that both the U.S. Patent & Trademark Office database ([www.uspto.gov](http://www.uspto.gov)) and the front page of U.S. Patent No. 4,186,745, list inventor Kauzlarich, James J. as the second of two inventors, the first inventor being Lewis, David W. In light thereof, Applicant respectfully suggests that U.S. Patent No. 4,186,745 and inventor Kauzlarich are properly matched. Nonetheless, in an effort to expedite prosecution, Applicant also submits herewith a Fourth Supplemental Information Disclosure Statement, as requested by the Examiner, citing U.S. Patent No. 4,186,745 and listing inventor Lewis (under Name of patentee of cited document) on the Form 1449. The \$180.00 fee required under 37 C.F.R. § 1.97(c)(2) and 37 C.F.R. § 1.17(p) for submission of an Information Disclosure Statement after a non-final Office Action has been debited electronically from Barnes & Thornburg LLP Deposit Account No. 10-0435, with reference to our matter 41594-200407, at the time of submitting the instant Fourth Supplemental Information Disclosure Statement.

In the Office Action mailed February 27, 2006, claims 57-59, 62, 64, and 105-106 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Altman *et al.* (U.S. Patent No. 6,086,582). Claim 60 and claim 61 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Altman *et al.* (U.S. Patent No. 6,086,582) in view of Chupakhin *et al.* (U.S. Patent No. 6,028,068) and Donatsch *et al.* (U.S. Patent No.

4,789,673), respectively. Claim 63 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Altman *et al.* (U.S. Patent No. 6,086,582). Claims 65 and 104 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Altman *et al.* (U.S. Patent No. 6,086,582) in view of Ellinwood, Jr. (U.S. Patent No. 4,146,029).

**Rejection of Claims 57-59, 62, 64, and 105-106 Under 35 U.S.C. § 102(e)**

The Examiner rejected claims 57-59, 62, 64, and 105-106 under 35 U.S.C. § 102(e) as allegedly being anticipated by Altman *et al.* (U.S. Patent No. 6,086,582). On pages 3-4 of the Office Action, the Examiner specifically states that:

Altman et al. disclose a method of providing a compound to a system comprising a catheter having a drug which is releasably captured in the matrix , a source of electrical energy 1052 which is activated to release the drug from the matrix 1060 , a controller which senses electrical activity of the heart and responds by injecting delivery of the drug or goes into monitoring mode depending on the sensed electrical activity. See column 14, lines 7-47 and col. 14, line 66 to col. 15, line 47. With respect to claims 64, Altman et al. disclose the releasing of the drug depends on the sensed electrical activity and as such , it is considered to releasing predetermined amounts of compounds at variable intervals. See column 16, lines 2-8.

Applicant traverses the instant rejection, and respectfully submits that it is well settled that in order for a single reference to anticipate a claim under 35 U.S.C. § 102, that reference must include, either expressly or inherently, each and every element, *i.e.*, limitation, of the claim. *See*, for example, *In re Verdegaal*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Applicant's pending claims are directed to a method for providing a compound to a system comprising the following elements:

providing a compound releasably captured within a matrix material, the compound being releasable upon receiving an energy input, a source of energy, and a controller operatively connected to the source and using a control signal to operate the source;

preparing a control signal using fractal mathematics;

placing the matrix material and captured compound in fluid communication with the system; and

operating the controller with the control signal and providing energy to the matrix material sufficient to release a portion of the compound into the system.

(emphasis added)

Applicant's instantly rejected claims include independent claim 57 and dependent claims 58-59, 62, 64, and 105-106. Each of these claims recite all of the above elements. However, Altman *et al.* is completely silent as to the use of fractal mathematics. As such, Altman *et al.* lacks all of the elements, *i.e.*, limitations, of claim 57, as well as claims 58-59, 62, 64, and 105-106. Therefore, Altman *et al.* does not anticipate the instant claims, or any other claim depending from claim 57. Accordingly, Applicant respectfully requests that the instant rejection under 35 U.S.C. § 102(e) be withdrawn.

If, after considering the above argument, the Examiner maintains the instant rejection, Applicant respectfully requests the Examiner to point out, with particularity (*i.e.*, by column number and line number, etc.), where in Altman *et al.* the use of fractal mathematics is either taught or suggested.

**Rejection of Claim 60 Under 35 U.S.C. § 103(a)**

The Examiner rejected claim 60 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Altman *et al.* (U.S. Patent No. 6,086,582) in view of Chupakhin *et al.* (U.S. Patent No. 6,028,068). On pages 4-5 of the Office Action, the Examiner specifically states that "Altman *et al.* discloses the invention as substantially claimed" and that "Altman *et al.* teach treating the cardiac system or circulatory system of a biological unit with cardiac agents." The Examiner further specifically states that:

However, Altman *et al.* does not disclose the therapeutic agent is anesthetic and the system to be the neurological system. Chupakhin *et al.* teach 6H-1,3,4-thiadiazin-2-amines drugs used in medicine acting as anesthetics, cardiovascular and hypometabolic agents. Specifically, Chupakhin *et al.* teaches that anesthetic agents act as respiratory and cardiovascular depressants. Further, agents have been identified as having an anesthetic and cardiovascular property, which are used in brain and myocardial infarction. Anesthetics are a drug class which is well known for acting on the neurological system. It would have been obvious to one of ordinary skill in the anesthesia art to substitute the cardiovascular drug of Altman *et al.* with the 6H-1,3,4-thiadiazin-2-amines which could treat the patient in a life-threatening situation with the properties of being an anesthetic and cardiovascular agent which act on the circulatory and neurological system.

Applicant traverses the instant rejection, and respectfully submits that it is well settled that in order for one or more references to establish a *prima facie* case of obviousness under 35 U.S.C. § 103, three basic criteria must be met. As per MPEP § 2143: "First, there

must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.” (emphasis added) Further, the teaching or suggestion to make a claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *See*, In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). *See also*, In re Lee, 277 F.3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002), which discusses the importance of relying on objective evidence and making specific factual findings with respect to the motivation to combine references.

Applicant's pending claim 60, which claim depends directly from claim 57, is directed to a method for providing a compound to a system, and reads as follows when written in independent form:

60. A method for providing a compound to a system comprising:

providing a compound releasably captured within a matrix material, the compound being releasable upon receiving an energy input, a source of energy, and a controller operatively connected to the source and using a control signal to operate the source;

preparing a control signal using fractal mathematics;

placing the matrix material and captured compound in fluid communication with the system; and

operating the controller with the control signal and providing energy to the matrix material sufficient to release a portion of the compound into the system,

wherein the system is the neurological system of a biological unit and the therapeutic agent is an anesthetic.  
(emphasis added)

As discussed above, Altman *et al.* is completely silent as to the use of fractal mathematics. Likewise, Chupakhin *et al.* is also completely silent as to the use of fractal mathematics. Thus, the proposed combination of Altman *et al.* and Chupakhin *et al.* neither teaches nor suggests all the limitations of claim 60. Further, Applicant respectfully point out that there is no suggestion or motivation to combine Altman *et al.* with Chupakhin *et al.*, since Altman *et al.* describes the localized delivery of a therapeutic agent to a depth within cardiac tissue, whereas Chupakhin *et al.* describes compounds that appear to require systemic delivery. Therefore, Applicant respectfully submits that a *prima facie* case of obviousness

under 35 U.S.C. § 103 has not been established. Accordingly, Applicant respectfully requests that the instant rejection under 35 U.S.C. § 103(a) be withdrawn.

If, after considering the above argument, the Examiner maintains the instant rejection, Applicant respectfully requests the Examiner to point out, with particularity (*i.e.*, by column number and line number, etc.), where in either Altman *et al.* or Chupakhin *et al.* the use of fractal mathematics is either taught or suggested.

**Rejection of Claim 61 under 35 U.S.C. § 103(a)**

The Examiner also rejected claim 61 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Altman *et al.* (U.S. Patent No. 6,086,582) in view of Donatsch *et al.* (U.S. Patent No. 4,789,673). On page 5 of the Office Action, the Examiner specifically states that “Altman et al. discloses the invention as substantially claimed” and that “Altman et al. teach treating the cardiac system or circulatory system of a biological unit with cardiac agents.” The Examiner further specifically states that:

However, Altman et al. is silent to a neurotransmitter as an agent in the neurological system of the biological unit. Donatsch et al. teach serotonin M receptor antagonists for the treatment of pain, migraine, vascular and treatment of heart circulation disorders. Serotonin receptors are located in the nervous system of the GI track, the **heart**, the bladder and the adrenal glands. It would have been obvious to one of ordinary skill in the medical art to substitute the cardiovascular drug of Altman et al. with another cardiovascular drug such as the Serotonin M receptor antagonist of the Donatsch et al. to treat heart circulation disorders.

Applicant traverses the instant rejection, and respectfully directs the Examiner’s attention to the **Rejection of Claim 60 under 35 U.S.C. § 103(a)** above, wherein Applicant describes the criteria that must be met for one or more references to establish a *prima facie* case of obviousness under 35 U.S.C. § 103.

Applicant’s pending claim 61, which claim depends directly from claim 57, is directed to a method for providing a compound to a system, and reads as follows when written in independent form:

61. A method for providing a compound to a system comprising:

providing a compound releasably captured within a matrix material, the compound being releasable upon receiving an energy input, a source of energy, and a controller operatively connected to the source and using a control signal to operate the source;

preparing a control signal using fractal mathematics;

placing the matrix material and captured compound in fluid communication with the system; and

operating the controller with the control signal and providing energy to the matrix material sufficient to release a portion of the compound into the system,

wherein the system is the neurological system of a biological unit and the therapeutic agent is a neurotransmitter.  
(emphasis added)

As discussed above, Altman *et al.* is completely silent as to the use of fractal mathematics. Likewise, Donatsch *et al.* is also completely silent as to the use of fractal mathematics. Thus, the proposed combination of Altman *et al.* and Donatsch *et al.* neither teaches nor suggests all the limitations of claim 61. Further, Applicant respectfully points out that there is no suggestion or motivation to combine Altman *et al.* with Donatsch *et al.*, since Altman *et al.* describes the localized delivery of a therapeutic agent to a depth within cardiac tissue, whereas Donatsch *et al.* describes compounds that appear to require systemic delivery. Therefore, Applicant respectfully submits that a *prima facie* case of obviousness under 35 U.S.C. § 103 has not been established. Accordingly, Applicant respectfully requests that the instant rejection under 35 U.S.C. § 103(a) be withdrawn.

If, after considering the above argument, the Examiner maintains the instant rejection, Applicant respectfully requests the Examiner to point out, with particularity (*i.e.*, by column number and line number, etc.), where in either Altman *et al.* or Donatsch *et al.* the use of fractal mathematics is either taught or suggested.

#### **Rejection of Claim 63 Under 35 U.S.C. § 103(a)**

The Examiner also rejected claim 63 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Altman *et al.* (U.S. Patent No. 6,086,582). On page 6 of the Office Action, the Examiner specifically states that “Altman et al. discloses the invention as substantially claimed.” The Examiner further specifically states that:

However, Altman et al. is silent to the control signal having a frequency content of less than about 1 Hz. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the frequency to about 1 HZ since it lacks criticality and this parameter is deemed matters of choice well within the general skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

Applicant traverses the instant rejection, and respectfully directs the Examiner's attention to the Rejection of Claim 60 under 35 U.S.C. § 103(a) above, wherein Applicant describes the criteria that must be met for one or more references to establish a *prima facie* case of obviousness under 35 U.S.C. § 103.

Applicant's pending claim 63, which claim depends directly from claim 57, is directed to a method for providing a compound to a system, and reads as follows when written in independent form:

63. A method for providing a compound to a system comprising:

providing a compound releasably captured within a matrix material, the compound being releasable upon receiving an energy input, a source of energy, and a controller operatively connected to the source and using a control signal to operate the source;

preparing a control signal using fractal mathematics;

placing the matrix material and captured compound in fluid communication with the system; and

operating the controller with the control signal and providing energy to the matrix material sufficient to release a portion of the compound into the system,

wherein the control signal has a frequency content generally less than about 1 Hertz.  
(emphasis added)

As discussed above, Altman *et al.* is completely silent as to the use of fractal mathematics. Thus, Altman *et al.* does not teach or suggest the use of fractal mathematics, nor does Altman *et al.* infer in any way the use of fractal mathematics. Further, Applicant respectfully points out that there is no suggestion or motivation, either in Altman *et al.* or in the knowledge generally available to one of ordinary skill in the art, to modify Altman *et al.* to arrive at Applicant's claim 63. Therefore, Applicant respectfully submits that a *prima facie* case of obviousness under 35 U.S.C. § 103 has not been established. Accordingly, Applicant respectfully requests that the instant rejection under 35 U.S.C. § 103(a) be withdrawn.

If, after considering the above argument, the Examiner maintains the instant rejection, Applicant respectfully requests the Examiner to point out, with particularity (*i.e.*, by column number and line number, etc.), where in Altman *et al.* the use of fractal mathematics is either taught or suggested.

**Rejection of Claims 65 and 104 Under 35 U.S.C. § 103(a)**

The Examiner also rejected claims 65 and 104 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Altman *et al.* (U.S. Patent No. 6,086,582) in view of Ellinwood, Jr. (U.S. Patent No. 4,146,029). On page 6 of the Office Action, the Examiner specifically states that “Altman et al. discloses the invention as substantially claimed,” and that “Altman et al. teach treating the cardiac system or circulatory system of a biological unit with cardiac agents...and teach a controller for releasing an amount of drug at variable intervals” On pages 6-7 of the Office Action, the Examiner further specifically states that:

However, Altman is silent to releasing variable amounts of the compound at predetermined intervals or releasing variable amounts of the drug at variable intervals. Ellinwood, Jr. teaches a programmable controller for a medication system . See figures 1-11. Ellinwood, Jr. teaches 1/ sensing , timed evaluation, with decision control, 2/ periodic sensing and screening control, 3/ periodic sensing , data evaluation with dosage control, 4/ periodic sensing, data evaluation and alternate dosage selection , and 5/ sensing , controlled same dosage within different amounts for different conditions. See column 3, lines 9-46 and column 4, lines 39-42. Ellinwood, Jr. further discloses that a large number of variables can be programmed to match both the immediate and changing conditions of a wide range of patient needs. Thus, it would have been obvious to modify the predetermined amount of the drug and/or the interval time of Altman et al. with variable amounts of drug and/or variable interval times as taught by Ellinwood, Jr. in order to provide a more effective treatment method for the varying need of the patient condition.

Applicant traverses the instant rejection, and respectfully directs the Examiner’s attention to the **Rejection of Claim 60 under 35 U.S.C. § 103(a)** above, wherein Applicant describes the criteria that must be met for one or more references to establish a *prima facie* case of obviousness under 35 U.S.C. § 103.

Applicant’s pending claims 65 and 104, which claims depend directly from claim 57, are directed to a method for providing a compound to a system, and read as follows when written in independent form:

65. A method for providing a compound to a system comprising:

providing a compound releasably captured within a matrix material, the compound being releasable upon receiving an energy input, a source of energy, and a controller operatively connected to the source and using a control signal to operate the source;

preparing a control signal using fractal mathematics;

placing the matrix material and captured compound in fluid communication with the system; and

operating the controller with the control signal and providing energy to the matrix material sufficient to release a portion of the compound into the system,

wherein said operating includes releasing variable amounts of compound at predetermined intervals.  
(emphasis added)

104. A method for providing a compound to a system comprising:

providing a compound releasably captured within a matrix material, the compound being releasable upon receiving an energy input, a source of energy, and a controller operatively connected to the source and using a control signal to operate the source;

preparing a control signal using fractal mathematics;

placing the matrix material and captured compound in fluid communication with the system; and

operating the controller with the control signal and providing energy to the matrix material sufficient to release a portion of the compound into the system,

wherein said operating includes releasing variable amounts of compound at variable intervals.  
(emphasis added)

As discussed above, Altman *et al.* is completely silent as to the use of fractal mathematics. Likewise, Ellinwood, Jr. is also completely silent as to the use of fractal mathematics. Thus, the proposed combination of Altman *et al.* and Ellinwood, Jr. neither teaches nor suggests all the limitations of claims 65 and 104. Further, Applicant respectfully points out that there is no suggestion or motivation to combine Altman *et al.* with Ellinwood, Jr., since Altman *et al.* describes the localized delivery of a therapeutic agent to a depth within cardiac tissue, whereas Ellinwood, Jr. describes compounds that appear to require systemic delivery. Therefore, Applicant respectfully submits that a *prima facie* case of obviousness under 35 U.S.C. § 103 has not been established. Accordingly, Applicant respectfully requests that the instant rejection under 35 U.S.C. § 103(a) be withdrawn.

If, after considering the above argument, the Examiner maintains the instant rejection, Applicant respectfully requests the Examiner to point out, with particularity (*i.e.*, by column number and line number, etc.), where in either Altman *et al.* or Ellinwood, Jr. the use of fractal mathematics is either taught or suggested.

## CONCLUSION

The foregoing remarks are believed to be fully responsive to the various rejections raised by the Examiner in the February 27, 2006 Office Action. Applicant submits that this application is in condition for allowance, and respectfully request passage of the application to issuance.

The undersigned would welcome a telephonic interview with the Examiner if the Examiner believes that such an interview would facilitate resolution of any outstanding issues.

Respectfully submitted,  
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